



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

AT

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/194,552 | 03/23/1999 | PETER BROOKS | TSRI481.2 | 3335 |

7590 06/25/2004

THE SCRIPPS RESEARCH INSTITUTE
10550 NORTH TORREY PINES ROAD
MAIL DROP TPC 8
LA JOLLA, CA 92037

EXAMINER

HARRIS, ALANA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| | 1642 |

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/194,552 | BROOKS ET AL. | |
| | Examiner Alana M. Harris, Ph.D. | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 November 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 60,65-84 and 88-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 88-108 is/are allowed.
- 6) Claim(s) 60 and 65-84 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 60, 65-84 and 88-108 are pending.

Claims 61-64 and 85-87 have been cancelled.

Claims 88-108 have been added.

Claims 60, 65-84 and 88-108 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 U.S.C. § 112

3. The rejection of claims 60 and 65-84 set forth in Paper number 25, mailed May 21, 2003 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of Applicants' claim amendments. Claims 61, 62 and 85-87 have been cancelled.

Claim Objections

4. Claim 60 is objected to because of the following informality: it repeats SEQ ID NO: 15 twice. Applicants should delete one of the "15" recitation.

New Grounds of Rejection***Claim Rejections - 35 U.S.C. § 112***

5. Claims 60 and 65-84 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 60 broadly states “[a] method for inhibiting $\alpha_v\beta_5$ mediated angiogenesis... comprising administering ...an angiogenesis-inhibiting amount of an $\alpha_v\beta_5$ antagonist, wherein said antagonist is a matrix metalloproteinase polypeptide that *includes* an amino acid residue sequence shown in SEQ ID NO: [11-15, 17 and 19-22].” Applicants have not provided sufficient evidence that they were in possession of the infinite number of polypeptides that include the denoted sequences. In essence the sequences are amongst undefined amino acid residues that may exist on the amino- and carboxy- termini of SEQ ID NO: 11-15, 17 and 19-22. Applicants are not in possession of the plethora of polypeptides that comprise the defined sequences of SEQ ID NO: 11-15, 17 and 19-22. Moreover, the antagonist could be just a single amino acid residue as set forth in claim 60, lines 5 and 6.

Applicants must disclose a representative number of species when claims read on an entire genus. Applicants’ claims embody a host of antagonists, which has not been provided within the specification. Applicants seem to only be in possession of $\alpha_v\beta_5$ antagonists consisting of SEQ ID NO: 11-15, 17 and 19-22.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of the matrix metalloproteinase polypeptide antagonists consisting of SEQ ID NO: 11, 12, 13, 14, 15, 17, 19, 20, 21 and 22, the skilled artisan cannot envision the detailed structure or activity of potential antagonists comprising any one of the said sequences and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA..." requires a precise definition, such as by

structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

The specification does not evidence the possession of all the polypeptides that include the defined $\alpha_v\beta_5$ antagonists consisting of SEQ ID NO: 11-15, 17 and 19-22 which may or may not be capable of inhibiting angiogenesis. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph. unnecessarily and improperly extensive and undue.

Allowable Subject Matter

6. Claims 88-108 are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, but can normally be reached between the hours, 6:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Y. Chan can be reached on (703) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
22 June 2004